

## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
(PCT Article 36 and Rule 70)

REC'D 23 FEB 2005

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Applicant's or agent's file reference KJL/CT/P5127	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB 03/05348	International filing date (day/month/year) 09.12.2003	Priority date (day/month/year) 09.12.2002
International Patent Classification (IPC) or both national classification and IPC A61M5/162		
Applicant ZI MEDICAL PLC et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I  Basis of the opinion
- II  Priority
- III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV  Lack of unity of invention
- V  Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI  Certain documents cited
- VII  Certain defects in the international application
- VIII  Certain observations on the international application

Date of submission of the demand 28.06.2004	Date of completion of this report 21.02.2005
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**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/GB 03/05348

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-9 as originally filed

**Claims, Numbers**

1-32 filed with telefax on 19.08.2004

**Drawings, Sheets**

1/6-6/6 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

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5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	1-32
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-32
Industrial applicability (IA)	Yes: Claims	1-32
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

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**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

- D1: US 2002/115981 A1 (WESSMAN GORAN) 22 August 2002 (2002-08-22)
- D2: US-A-3 359 977 (BURKE GEORGE K) 26 December 1967 (1967-12-26)
- D3: US-A-3 662 752 (YOKOYAMA KOUSOU) 16 May 1972 (1972-05-16)
- D4: US-A-4 787 898 (RAINES KENNETH C) 29 November 1988 (1988-11-29)
- D5: US-A-4 857 068 (KAHN PAUL) 15 August 1989 (1989-08-15)
- D6: US-A-4 623 343 (THOMPSON THOMAS C) 18 November 1986 (1986-11-18)

**1. The subject-matter of claim 1 is not inventive (Article 33(3) PCT).**

The most relevant prior art is disclosed in D1, which teaches a giving set cap (10) for providing fluid communication between two vessels (20, and a drip chamber). The cap has a delivery tube (11) with a main channel (13) for delivering fluid from the first vessel to the second vessel, and a subsidiary channel (14) for the delivery of a different material to said first vessel (20).

The cap has also an inlet opening (opening at the top end of main channel (13)) for delivering fluid from the first vessel through the main channel, the inlet being spaced at a sufficient distance from an outlet (at the top end of delivery tube (11)) of the subsidiary channel to allow mixing of the different material with said fluid prior to delivery to said other vessel.

The subject-matter of claim 1 differs from the known giving set cap in that an inlet (45) of the subsidiary channel is adapted to receive a needleless syringe.

Giving set caps providing inlets adapted to receive a needleless syringe have been known since long in the prior art, an example being shown in D3, injection port (16, 17), but also in D4 and D5. These injection ports form part of the general knowledge of any skilled person, who would automatically provide such a port if this was found convenient, e.g. because of the need to avoid the risk of needle stick injuries. Thus, a giving set cap according to claim 1 is not inventive without even having to combine the teachings of either D3, D4 or D5 with that of D1.

Further, applicant's argumentation "that D1 did not consider ports for receiving

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needleless syringes although these ports were known before the filing date of D1" was not convincing at all. The fact that D1 does not disclose ports for needleless syringes means that the inventors of D1 did not want to provide such ports for whatever reason, and that the combination of features of claim 1 is novel. It does, however, not automatically also involve an inventive step.

2. The additional features of claims 2-25 do not appear to render the subject-matter of any claim to which said features are referred to inventive (Article 33(3) PCT). The features are either already disclosed in D1, or represent mere matter of normal design alternatives the skilled man is readily aware of, or are rendered obvious when considering the teaching of D2, or D3.

Claims 2-7: the particular spacing of 10, 20 or 25 mm between the inlet and the outlet appears to be around the spacing present in D1. D6 further teaches that the outlet has to be sufficiently distanced from the inlet in order to avoid air bubbles been drawn back down by the exiting fluid. D1 discloses a giving set chamber (12), and tapered piercing means for connection to an IV bag.

Claims 8-11: a "rounded" spike is not inventive, and the one of D3 can also be considered as "rounded". At least two inlets, or three inlets for the main channel (claims 10, 11) are not inventive, as this is part of the general knowledge for the skilled person.

Claims 12-22: cf. D1, a detachable cover functioning as an air vent is disclosed in, e.g., D2 and D3, and the remaining additional features do not appear to solve any particular objective technical problem.

Claims 23-25: A drip chamber connected to the giving set cap is disclosed in D1, a threaded connection thereof is taught by D2, Fig. 1 and 2.

3. The reasoning given under 1. above is equally applicable to the subject-matter of claim 26, which essentially is the same as that defined in claim 1 (cf. also Further comments, 1.). For the dependent claims 27-32, cf. the reasoning for the corresponding ones of claims 2-25 that define the same features.

**Further comments:**

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1. Although **claims 1 and 26** have been drafted as separate independent claims, they relate effectively to the **same subject-matter**, i.e. there is **overlapping scope**, and differ from each other only with regard to the definition of the subject-matter for which protection is sought or in respect of the terminology used for the features of that subject-matter.

The aforementioned claims therefore **lack conciseness** (Article 6 and Rule 6.1(a) PCT).

The relevant subject-matter should have been defined in a **single independent claim** followed by dependent claims covering features which are merely optional (Rules 6.3 and 6.4 PCT).

In particular, except for the first two lines of claim 26, the definition given coincides with the wording of claim 1. I.e. claim 26 is actually dependent on claim 1, and therefore, recurrent wording should have been avoided. Claim 26 should have been explicitly referred back to claim 1.

2. The **single independent claim** should have been cast in the **two-part form** (Rule 6.3(b) PCT) with the preamble containing those features known in combination from the closest prior art (**D1**) (Rule 6.3(b)(i) PCT). The features of all the claims should have been provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).
3. D1 should have been briefly discussed in the description.